

I. AMENDMENT

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

New claims 44-64 replace the previously pending claims, which are canceled.

1-43. (Canceled)

44. (New) A method of treating cancer comprising administering to a patient in need thereof:

(a) an admixture comprising a cancer or tumor antigen expressed by cells of the cancer to be treated and a microfluidized antigen formulation comprising:

- (i) a stabilizing detergent,
- (ii) a micelle-forming agent, and
- (iii) a biodegradable and biocompatible oil,

said antigen formulation being formulated as a stable oil-in-water emulsion;

wherein said admixture is administered to said patient in an amount sufficient to induce a cytotoxic T-lymphocyte response in said patient which is specific for the cancer or tumor antigen contained in said admixture, and

(b) a therapeutically effective amount of at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of transforming growth factor β (TGF β) specifically;

wherein the antigen-containing admixture and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β are administered sequentially or concurrently, and in any order.

45. (New) The method of claim 44, wherein the antigen-containing admixture and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β are administered sequentially.

46. (New) The method of claim 44, wherein the antigen-containing admixture is administered intradermally, intramuscularly or subcutaneously and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β is administered intravenously.

47. (New) The method of claim 44, wherein the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β is selected from the group consisting of an anti-TGF β antibody, a TGF β R-fusion protein, a TGF β analog, a TGF β binding protein, and a TGF β R blocking antibody.

48. (New) The method of claim 47, wherein the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF β is a thrombospondin peptide or a TGF β R Fc-fusion protein.

49. (New) The method of claim 44, wherein the admixture comprises a cancer or tumor antigen selected from the group consisting of gp100, MART-1/Melan A, gp75, tyrosinase, melanoma proteoglycan, MAGE, BAGE, GAGE, RAGE, N-acetylglucosaminyltransferase-V, mutated B-catenin, mutated MUM-1, mutated cyclin dependent kinases-4, p21 ras, BCR-abl, p53, p185 HER2/neu, mutated epidermal growth factor receptor, carcinoembryonic antigens, carcinoma associated mutated mucins, Epstein Barr nuclear antigen (EBNA) gene products, papillomavirus E7 protein, papillomavirus E6 protein, prostate specific antigens, prostate specific membrane antigen, and prostate carcinoma tumor antigen-1 (PCTA-1).

50. (New) The method of claim 44, wherein the cancer is selected from the group consisting of breast cancer, brain cancer, cervical cancer, leukemia, lymphoma, prostate cancer, skin cancer, colon cancer, lung cancer, ovarian cancer, pancreatic cancer, liver cancer, bladder cancer, kidney cancer, myeloma, colorectal cancer, nasopharyngeal carcinoma, or endometrial cancer.

51. (New) The method of claim 44, wherein the detergent is provided in an amount ranging from approximately 0.05 to 0.5%.

52. (New) The method of claim 52, wherein the amount of detergent is about 0.2%.

53. (New) The method of claim 44, wherein the detergent is selected from the group consisting of TWEEN 80, TWEEN 20, TWEEN 40, TWEEN 60, Zwittergent 3-12, TEEPOL HB7 and SPAN 85.

54. (New) The method of claim 44, wherein the micelle-forming agent has a hydrophile-lipophile balance of between 0 and 2.

55. (New) The method of claim 44, wherein the amount of the micelle-forming agent ranges from 0.5 to 10%.

56. (New) The method of claim 55, wherein the amount of the micelle-forming agent ranges from 1.25 to 5%.

57. (New) The method of claim 44, wherein the micelle-forming agent is selected from the group consisting of poloxamer 401, PLURONIC L62Lf, PLURONIC L101, PLURONIC L64, PEG1000, TETRONIC 1501, TETRONIC 150R1, TETRONIC 701, TETRONIC 901, TETRONIC 1301 and TETRONIC 130R1.

58. (New) The method of claim 44, wherein the amount of oil ranges from 1 to 10%.

59. (New) The method of claim 58, wherein the amount of oil ranges from 2.5 to 5%.

60. (New) The method of claim 44, wherein the oil exhibits a melting temperature of less than 65°C.

61. (New) The method of claim 44, wherein the oil is selected from the group consisting of squalane, eicosane, tetratetracontane, pristane, and vegetable oils.

62. (New) The method of claim 44, wherein the antigen-containing admixture comprises TWEEN 80, poloxamer 401, and squalane.

63. (New) The method of claim 44, wherein the antigen-containing admixture contains no more than 20 micrograms of an immunostimulating peptide.

64. (New) The method of claim 44, wherein the antigen-containing admixture lacks an immunostimulating peptide.